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DEPARTMENT OF HEALTH AND HUMAN SERVICES

US Food and Drug Administration

21 CFR Part 173

[Docket No. 00F-1482]

Secondary Direct Food Additives Permitted in Food for Human Consumption

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of ozone in gaseous and aqueous phases as an antimicrobial agent on food, including meat and poultry. This action is in response to a petition filed by the Electric Power Research Institute, Agriculture and Food Technology Alliance.

DATES: This rule is effective June 26, 2001. Submit written objections and requests for a hearing by July 26, 2001. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of a certain publication listed in Sec. 173.368(c), effective as of June 26, 2001.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204-0001, 202-418-3074.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of September 13, 2000 (65 FR 55264), FDA announced that a food additive petition (FAP 0A4721) had been filed by the Electric Power Research Institute, Agriculture and Food Technology Alliance, 2747 Hutchinson Ct., Walnut Creek, CA 94598. The petition proposed to amend the food additive regulations in part 173 (21 CFR part 173) to provide for the safe use of ozone in gaseous and aqueous phases as an antimicrobial agent for the treatment, storage, and processing of foods.

List of Subjects in 21 CFR Part 173

Food additives, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 173 is amended as follows:

PART 173--SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. Section 173.368 is added to subpart D to read as follows:

Sec. 173.368 Ozone.

Ozone (CAS Reg. No. 10028-15-6) may be safely used in the treatment, storage, and processing of foods, including meat and poultry (unless such use is precluded by standards of identity in 9 CFR part 319), in accordance with the following prescribed conditions:
(a) The additive is an unstable, colorless gas with a pungent, characteristic odor, which occurs freely in nature. It is produced commercially by passing electrical discharges or ionizing radiation through air or oxygen.
(b) The additive is used as an antimicrobial agent as defined in Sec. 170.3(o)(2) of this chapter.
(c) The additive meets the specifications for ozone in the Food Chemicals Codex, 4th ed. (1996), p. 277, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20055, or may be examined at the Office of Premarket Approval (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC, and the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.
(d) The additive is used in contact with food, including meat and poultry (unless such use is precluded by standards of identity in 9 CFR part 319), in the gaseous or aqueous phase in accordance with current industry standards of good manufacturing practice.
(e) When used on raw agricultural commodities, the use is consistent with section 201(q)(1)(B)(i) of the Federal Food, Drug, and Cosmetic Act (the act) and not applied for use under section 201(q)(1)(B)(i)(I), (q)(1)(B)(i)(II), or (q)(1)(B)(i)(III) of the act.

Dated: June 15, 2001.
L. Robert Lake,
Director of Regulations and Policy, Center for Food Safety and Applied Nutrition.
[FR Doc. 01-15963 Filed 6-25-01; 8:45 am] BILLING CODE 4160-01-S